Alternatives Assessment Overview

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Purpose

- Society is driving companies like DuPont to make decisions based on more than just regulatory requirements.
- In response, DuPont has developed a Framework to formalize an approach to making informed decisions about chemical selection.
- Our Framework attempts to address the interests of a variety of stakeholders.
- As an important stakeholder, we'd like to share our Framework with you and get your feedback.

Goal: Efficient, consistent, complete

- Streamlined methodology
- Flexible: useful for multiple users
- Address the interests of a variety of stakeholders.
- Practical: based on business experience

Development

- Literature search
- Internal business interviews and mapping
- Gap analysis to include stakeholder interests
- Pilot and upgrade

Proposed Alternatives Assessment Framework

Set Baseline Conditions



Identify Feasible Alternatives
Based on Functionality

Compare Baseline and Alternatives



Decide Among Alternatives

Alternatives Assessment Framework

I. Set Baseline Conditions

- Identify target chemical
- Identify the driver for conducting the assessment
- Identify the end goal (e.g., lower residual, substitution, reduction of specific exposure)
- Establish the Product Trail

II. Identify Feasible Alternatives

- Identify attributes/functionality that an alternative MUST have
- Engage other regions/existing supplier for alternatives info
- Conduct brainstorming session with business/R&D experts to consider:
 - Drop-in chemical replacements
 - Process change with chemical replacement
 - Product redesign to reduce concentration of COC
 - Product redesign to reduce exposure potential during manufacture, use or disposal
 - Product redesign to improve reuse/recycling
- Explore commercial availability/feasibility of alternatives
- Identify potential, functional alternatives (iterative process)

Framework (cont'd)

III. Compare Baseline and Alternatives

- -Compare the following criteria
 - -Performance
 - -Manufacturability
 - -Human Health Profile
 - -Environmental Profile
 - -Safety
 - -Economic Feasibility
 - -Market Impact /Green Labeling Opportunities
 - -Screening Life Cycle Assessment (energy/water/emissions)
 - -Exposure Potential throughout Product Trail
 - -Social Considerations/Stakeholder Buy-In
- -Use guidance tools/best practices to populate template

IV. Decide

- -Refine business factors for decision-making
- -Decide whether to stay with baseline or pursue an alternative
- -Document rationale, as needed
- -If alternative is selected, make a plan with a clear timeline

Template

Target Chemical:	Driver:						
End Goal:							
Function of Target Chemical:							
	BASELINE	ALTERNATIVES					
Criteria							
Chemical Name							
Structure							
CAS No.							
Performance							
Manufac turability							
Human Health Profile (e.g., CMR,							
endocrine activity)							
Environmental Profile (PB and aquatic							
to xicity)							
Safety							
Facultiii							
Economic Feasibility							
Market Impact/Green Labeling							
Opportunities							
Screening Life Cycle Assessment (energy,							
resource use, water use)							
Exposure Potential throughout product							
trail							
Social Considerations/Stakeholder Buy-In							
(NGO, deselection and biomonitoring							
lists)							

Driver

Describe the voluntary or involuntary business rationale for conducting this Alternatives Assessment.

Baseline

Identify the compound or compounds that are targeted for the Assessment. You may wish to include a CAS Number and a graphic showing the structure of the compound.

Alternatives

Arriving at viable alternatives is often a long-term process that involves discussions with internal and external experts. Some businesses have elected to conduct brainstorming sessions and include members of R&D, marketing and even downstream customers. If downstream customers are included, stakeholder involvement can occur in early stages of the assessment.

Performance

Performance criteria and testing are strictly the purview the business conducting the assessment. It is important to establish a clear and finite set of functional performance criteria that will "make or break" the selection of an alternative. To describe differences in performance between the baseline and various alternatives, some businesses may wish to develop an index such as this:

-2 = Much worse than control

-1 = Worse than control

0=Same as control

+1 = Better than control

Manufacturability

Companies like DuPont believe that materials not currently commercially available can still be viable as long as the new material can be manufactured in sufficient quantities and in the near future (i.e., "manufacturability). It is important to recognize that new materials can as viable as existing materials, and allowing new materials can drive innovation. To describe differences in manufacturability between the baseline and various alternatives, some businesses may wish to develop an index such as this:

-2 = Much worse than control

-1 = Worse than control

0=Same as control

+1 = Better than control

Human Health Profile

There is no single list of human health criteria to compare alternatives against, as it would be unreasonably long. Rather, it is recommended that the toxicologists be engaged to lead this portion of the assessment to eliminate any candidates with obvious potential health issues and to

- 1. look <u>first</u> at any toxicity characteristics inherent in the baseline chemical that have been targeted as a concern and then
- 2. examine any remaining toxicological endpoints of interest that would allow a determination of whether one candidate has an overall improved toxicological profile versus the baseline or another candidate. Consider endpoints in the box¹ if they are relevant.
- 3. focus on toxicology aspects that are most relevant to the product and its application. For example, if a non-volatile material is used in an isolated system, inhalation exposure may not be very relevant.

Potential Endpoints

Acute

Cancer

Developmental

Endocrine Disruption

Genotoxicity/Mutagenicity

Immune System

Irritation/Corrosion - skin, eyes

Neurological

Reproductive

Sensitizer – respiratory, skin Systemic Toxicity/organ Effects

1. Rossi, M., Heine, L., 2007. Green Screen for Safer Chemicals: Evaluating Flame Retardants for TV Enclosures, Clean Production Action, Version 1.0

Environmental Profile

Similar to the Human Health Profile, the criteria used to compare environmental profiles should center on any environmental impacts that may be of concern for the baseline material. Persistence, tendency to bioaccumulate and aquatic toxicity are often important to consider in the absence of any other impact of concern. Various resources can assist in this assessment, including the EPA's PBT Profiler and Corporate fate and transport consultants.

Safety

Safety metrics are again tailored to the characteristics of the materials under consideration and the conditions of their handling and use. Potential to explode and flammability are examples of fundamental safety characteristics that could be considered. Process Safety and Fire Protection consultants can be helpful in assessing safety risks.

Economic Feasibility

Economic feasibility can be measured a number of ways. In many cases, raw material costs are a sufficient indicator of differences between options. In other cases, a more holistic approach (e.g., value-in-use assessment) would more appropriately demonstrate economic differences among alternatives. The appropriate choice is made by the business conducting the assessment. Engineering Evaluations consultants can be helpful in providing assistance.

Market Impact/Green Labeling Opportunities

Changes to a product formulation could present hurdles or opportunities in the marketplace. An important part of assessing the impact of a substitute material is to understand how the market (downstream customers and ultimate consumers) may react to the reformulation. If the substitution could be perceived as beneficial, the business may wish to consider labeling/advertising changes. If Green Labeling opportunities are explored, note that there are resources who can help interpret external green labeling standards.

Screening Life Cycle Assessment (energy, resource consumption, carbon footprint, ghg)
Life Cycle Assessments are typically performed to evaluate the carbon footprint of a process (from cradle to grave) including energy use, natural resource consumption, and generation of emissions.

Sustainability Analysis resources are available to assist in these assessments.

Exposure Potential Throughout Product Trail

Toxicity characteristics alone do not dictate the risk of a particular chemical. Potential exposure during manufacture, use and disposal must also be considered to get a full picture of potential risk. Using the product trail, consider exposure to workers, to downstream industrial customers, to consumers (if the chemical is used in consumer products) and to the general public who could be exposure to emissions during manufacture or disposal of the material. This analysis may be qualitative or quantitative in nature, concentrating on potential differences in exposure along the product trail.

Social Considerations/Stakeholder Buy-In

Stakeholder acceptance is an important factor that can make or break a product's success in the market place. While industry should still rely on sound science and risk-based approaches to accurately assess viability and potential risk, it is important to "take the pulse" of the public regarding the use of certain materials. Understanding stakeholder viewpoints can be achieved directly by engaging the downstream customers/consumers who will be impacted by product redesign or reformulation.

Salient Points About Framework

- We believe good decision-making involves a broader spectrum of criteria that cover multi-stakeholder interests.
- The Framework includes four basic steps that are not new, but lend themselves to an organized methodology.
- The Framework includes a template for organizing the information plus guidance for obtaining the necessary information.
- Specific decision-making rules are not included because a "one-size-fits all" approach is unworkable given the diversity of businesses products and processes.

Case study

Target Chemical: Solvent Z Driver: Reproductive Toxicant under REACH												
End Goal: Replace Solvent Z with non-CMR, low toxicity risk, more sustainable sustainable chemistry												
Function of Target Chemical: Solubilize/Coalesce binder polymers PolyAmidelmide and PolyEtherSulfone												
-2 = Much worse than control				Very significant disadvantage								
-1 = Worse than control				Significant disadvantage								
0=Same as control				Potential disadvantage								
+1 = Better than control				No known advantage/disadvantage vs. control								
					Slight adva	intage						
					Important a	dvantage						

	Baseline	Alternatives →						
Chemical	Salvant 7	O Hoversting 4	O Hoversting 2	O Hovestino 2	O Hovestino d	Ottovnotivo 5		
Structure	Solvent Z	Alternative 1	Alternative 2	Alternative 3	Alternative 4	Alternative 5		
CAS #				<u> </u>	[
Performance*	0	0	0	0	Not fully tested	Not fully tested		
Manufacturability*	0	-1 (viscosity)	0	0	0	-2 (corrosive & odor)		
Human Health Profile (eg CMR, endocrine activity)	Reproductive Toxicant under REACH	Not a CMR Mild Hypnotic	Not a CMR	Not a CMR	Corrosive to skinleye	Acute oral toxicity; CMR status unknown		
Safetg	Some potential for flammability and reactivity	Lower potential for flammability and reactivity	Lower potential for flammability and reactivity	Lower potential for flammability and reactivity	Some potential for flammability and reactivity	Lower potential for flammability and reactivity		
Environmental Profile (PB and aquatic toxicity)	Not considered persistent or bioaccumulative (PBT profiler)		Nitrogen Emission					
Economic Feasibility (Cost/lb)	\$1.64/lb	\$2.05/lb	\$1.90/lb	\$12-17#b	\$8/lb volume not readily avail	\$2.40/lb (volume avail unk)		
Market Impact/Green Labeling Opportunities	Market would welcome replacement	TBD	TBD	Biobased route exists	TBD	Biobased route exists		
Life Cycle Assessment (energy, resource use, water use)	N/D	N/D	N/D	N/D	N/D	N/D		
Exposure Potential throughout trail	Controlled exposure to workers below TLV; no consumer exposure because not present in final product	Controlled exposure to workers below TLV; no consumer exposure because not present in final product	Controlled exposure to workers below TLV; no consumer exposure because not present in final product	Controlled exposure to workers below TLV; no consumer exposure because not present in final product	Controlled exposure to workers below TLV; no consumer exposure because not present in final product	Controlled exposure to workers below TLV; no consumer exposure because not present in final product		
Social Considerations/Stakeholder Buy-in (NGO, deselection and biomonitoring lists)	EU & US HPV	EU & US HPV	EU & US HPV			No regulatory or public concerns		